

# EXHIBIT 3

Patti Nemeth, M.D.

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UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF ILLINOIS

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IN RE DEPAKOTE: :  
RHEALYN ALEXANDER, :  
et al., : No.  
Plaintiffs, : 12-52-NJR-SCW  
vs. :  
ABBOTT LABORATORIES, :  
INC., :  
Defendant. :  
- - -

DEPOSITION UNDER ORAL EXAMINATION OF  
PATTI NEMETH, M.D.

9:00 a.m.

Rio Rancho, New Mexico

- - -

REPORTED BY: DANA SREBRENICK, CRR, CLR

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Golkow Technologies, Inc.  
877.370.3377 ph | 917.591.5672 fax  
deps@golkow.com

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1 BY MR. BROSS:

2 Q. In the new label, the new black box, it  
3 says, "Valproate should only be used to treat  
4 pregnant women with epilepsy or bipolar disorder  
5 if other medications have failed to control their  
6 symptoms or are otherwise unacceptable."

7 I'm reading the section under the birth  
8 defects. It says, "Pregnancy registry data show  
9 that maternal Valproate use can cause neural tube  
10 defects and other structural abnormalities, for  
11 example, craniofacial defects, cardiovascular  
12 malformations, and malformations involving various  
13 body systems."

14 And that "the rate of congenital  
15 malformations among babies born to mothers using  
16 Valproate is about four times higher than the rate  
17 among babies born to epileptic mothers using other  
18 antiseizure monotherapies."

19 And there's a section under the use in  
20 women of childbearing potential, it says, "Because  
21 of the risk to the fetus of decreased" -- there is  
22 a section in the use in women of childbearing  
23 potential that says, "Because of the risk to the  
24 fetus of decreased I.Q. and major congenital  
25 malformations, including the neural tube defects,

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1 which may occur very early in pregnancy, Valproate  
2 should not be administered to a woman of  
3 childbearing potential unless the drug is  
4 essential to the management of her medical  
5 condition."

6 And the reason I wanted to read those few  
7 sections is to see if you recall whether the 2004  
8 label at issue of Ms. Sansone had these sort of  
9 considerations or instructions?

10 A. I do recall --

11 MR. KLATT: Objection, form.

12 A. Okay. I do recall that these were  
13 potential side effects in pregnancies, risk to  
14 fetus, that is, the congenital malformations  
15 related to the neural tubes and craniofacial and  
16 cardiac, I did know this. I did not know -- I did  
17 not recall the degree of risk compared to other  
18 antiseizure meds.

19 BY MR. BROSS:

20 Q. If you'd known the four times higher  
21 risk, would that have figured into your  
22 prescribing habits?

23 MR. KLATT: Objection, form and  
24 foundation.

25 MR. OTT: Object on speculation. Subject

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1 to that, try to answer it best as you can.

2 A. Can I ask you what it said in 2004?

3 BY MR. BROSS:

4 Q. Yeah, I'll show you '04, but I can tell  
5 you it did not have the terminology about four  
6 times higher risk.

7 MR. KLATT: Objection, form.

8 A. But I did -- okay. I did know that it  
9 was a higher risk. I -- but I didn't know how  
10 high it was, but I certainly knew it was greater.  
11 And let's see, I'm trying to remember, but I was  
12 thinking it was two or three times higher, is what  
13 I was thinking. So would I have done anything  
14 different?

15 I would have had the same discussion  
16 because there's still the question of is the drug  
17 essential to the patient, in this case the mother?  
18 And we would -- we would weigh the risks and --  
19 and determine whether or not we could choose  
20 another drug depending on when it is. Again, you  
21 can't do it during pregnancy.

22 So it is -- it's difficult to know  
23 exactly what I would have done if I had a  
24 different information than I had at the time.

25 MR. BROSS: I'd like to mark and show you

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1 Q. To be current?

2 MR. KLATT: Objection, form.

3 A. Well, yes, to be current.

4 BY MR. BROSS:

5 Q. And to not --

6 A. They actually supplement the PDR, so when  
7 things are different, we get a sheet and we put  
8 them at the back of the book after we look at  
9 them.

10 Q. And you would expect a company to  
11 supplement their labels in the PDR?

12 A. Oh, yes.

13 Q. And you may not be aware that or are you  
14 aware that this portion of the label remained the  
15 same until approximately 2008?

16 MR. KLATT: Objection, speculation.

17 A. I'm -- I'm not aware of when it changed  
18 or if it changed.

19 Q. And if the manufacturer, Abbott, had  
20 actual information about the overall incidence  
21 rates for malformations that were directly related  
22 to Depakote use, you would have wanted that to  
23 have been included in the label; is that correct?

24 MR. KLATT: Again, objection, form and  
25 foundation.

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1 A. Yes.

2 BY MR. BROSS:

3 Q. And may that have played a decision in  
4 your prescription decisions?

5 MR. KLATT: Objection, speculation.

6 A. Well, it would depend on the situation.

7 Q. But if the potential for increased  
8 congenital birth defects was actually four-fold  
9 higher, would that have been important for you to  
10 know?

11 MR. KLATT: Objection, form and  
12 foundation.

13 A. It would be important to know. But,  
14 again, without knowing exactly the situation at  
15 the time with the patient being pregnant, having  
16 seizures, tol -- not tolerating other medications,  
17 I don't know exactly what our conversation -- I  
18 know what our conversation would be about, but I  
19 don't know what the -- what decision we would come  
20 up with, but I would definitely talk to the  
21 patient.

22 Q. Is there anything here, though, that led  
23 you to believe or leads you to believe that  
24 Depakote is more teratogenic than other  
25 antiepileptics?

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CERTIFICATION

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4           I, DANA N. SREBRENICK, a Certified Court  
5   Reporter for and within the State of New Mexico,  
6   do hereby certify:

7           That the witness whose testimony as herein  
8   set forth, was duly sworn by me; and that the  
9   within transcript is a true record of the  
10   testimony given by said witness.

11           I further certify that I am not related to  
12   any of the parties to this action by blood or  
13   marriage, and that I am in no way interested in  
14   the outcome of this matter.

15           IN WITNESS WHEREOF, I have hereunto set my  
16   hand this 5th day of October 5, 2016.

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19           DANA N. SREBRENICK, CLR, CRR

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